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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,515	10/18/2001	Gary L. Bowlin	49122-0161 (49122-263824)	7220

23370 7590 05/20/2003

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EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/982,515

Applicant(s)

BOWLIN ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 Feb 02 & 19 Mar 02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,8,9,10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

*Status of the Claims*

Claims 1-23 have been presented for examination.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "further comprising placement of the composition in a bioreactor" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. What one does with the composition does not materially change the composition being claimed.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-8, 10-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffee RA (WO 98/03267) or under 35 U.S.C. 102(e) as being anticipated by the equivalent Coffee RA (US 6,252,129) (for convenience only the US patent will be cited).

Coffee RA (US 6,252,129) discloses electrohydrodynamically making fiber mats incorporating or having a core of biologically active ingredient or material for use in forming matter for application to a skin, a wound, a burn or a body cavity for example (column 1, lines 49-61). The fiber mats are prepared preferably from biodegradable polymers such as polylactic acid, polyglycolic acid, polyvinyl alcohol or polyhydroxybutyric acid (column 2, lines 48-57). Naturally occurring polymers such as fibrin or collagen, or electret polymers may also be used (column 3, lines 41-45). A wide range of biologically active ingredients may be incorporated, including cells (column 3, lines 23-40; column 3, line 66 to column 4, line 15).

Claims 1-2, 5-6, 8-15 and 17-23, are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. (US 4,043,331).

Martin et al. (US 4,043,331) disclose making a fibrillar mat with electrospun organic material (abstract) for use in particular as bandages. Various polymers may be used (column 4, lines 26-44; column 5, lines 21-29); the mats may be cross-linked (column 4, lines 40-44). Various biological components can be incorporated within the mat (column 2, lines 35-46).

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Claims 1-3, 5, 10-12 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Doshi et al. (1995).

Doshi et al. (1995) disclose making mats of electrospun fibers from poly(ethylene oxide) (PEO) solutions. It is suggested that the fibers can be used for applying insecticide to plants or as a wound dressing material, for example (page 159). Various polymers may be used such as water-soluble polymers, biopolymers and liquid crystalline polymers (page 152, second full paragraph).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee RA (WO 98/03267) or Coffee RA (US 6,252,129) in view of Martin et al. (US 4,043,331).

The teachings of Coffee RA (WO 98/03267) and Coffee RA (US 6,252,129) have been discussed above. Coffee RA (WO 98/03267) and Coffee RA (US 6,252,129) both lack cross-linked fibers.

A person of ordinary skill in the art at the time the invention was made would have been motivated to crosslink the fibrous mats of RA (WO 98/03267) and Coffee RA (US 6,252,129) as suggested by Martin et al. (US 4,043,331) because both Coffee RA (US 6,252,129) and Martin et

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al. (US 4,043,331) are making electroprocessed fibrous mats for similar purpose, as bandages incorporating biologically active material.

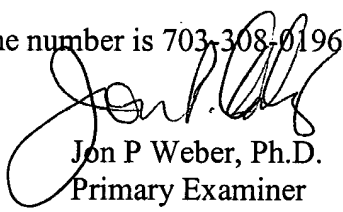
Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to crosslink the electroprocessed fibrous mats for the expected increased strength and stability of cross-linking.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
May 15, 2003